



Is Rulemaking Old Medicine at the FDA?

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I. Introduction

Agencies can create policy in three ways. The first is through case-by-case adjudication whereby an agency brings enforcement actions against various parties for violating the provisions of either a statute or a promulgated regulation that the agency is responsible for administering. The reasoning in the agency court's decisions in those actions establishes general rules defining what types of behavior are in compliance with the statute or regulation.¹ This type of policy-making is analogous to the creation of common law by the courts.

The second is through rulemaking² whereby an agency exercises legislative power delegated to it by Congress. A final rule usually represents a balancing of competing policies that the agency believes best furthers the objectives of the statute granting the agency its legislative authority. Most regulated parties voluntarily comply with the mandates of regulations because the regulations have the force of law. However, as alluded to above, an agency occasionally will have to bring an enforcement action against a regulated party to force the party to comply with a particular regulation. Such an action is

¹Case-by-case adjudication takes place as an agency adjudication whereby the agency conducts its own trial-like procedure to resolve the question presented in the action. An adjudication constitutes a final agency action which is subject to judicial review pursuant to §706 of the Administrative Procedure Act. One should note that the FDA does not have an adjudicatory branch and cannot engage in this type of policymaking.

²One should note that the FDA engages in both informal and formal rulemaking under the Food, Drug, and Cosmetic Act. §371(a) governs when the FDA should use informal rulemaking and §371(3) governs when the FDA should use formal rulemaking. This paper focuses only on informal rulemaking because the FDA infrequently engages in formal rulemaking. Any reference to "rulemaking" in this paper refers to informal rulemaking unless otherwise specified.

either an agency adjudication subject to judicial review or a court enforcement proceeding.

The third is through a more informal means whereby an agency embodies policy in informal opinions, guideline or guidance documents, operating manuals, or even press releases.³ This type of policy-making is the most informal, meaning that it incorporates the fewest procedural protections for regulated parties. In fact, there are no procedural requirements with which an agency must comply when generating policy in this fashion.

In the two decades following the enactment of the Administrative Procedure Act (“APA”),⁴ “licensing and rate-making proceedings, formal adjudications, as well as formal rulemakings dominated the administrative law landscape”.⁵ However, those regulatory mechanisms proved to be inappropriate for implementing the mass of new legislation passed in the late 1960’s and early 1970’s that sought to address health, safety, and environmental problems. Informal rulemaking quickly became the preferred means of instituting these new far-reaching governmental policies.⁶ Its procedures were less demanding and more democratic than those of adjudication and it made more sense to develop

³CARNEGIE COMMISSION ON SCIENCE, TECHNOLOGY, AND GOVERNMENT, RISK AND THE ENVIRONMENT: IMPROVING REGULATORY DECISION MAKING 106 (1993); Richard J. Pierce, Jr., *Seven Ways to Deossify Agency Rulemaking*, 47 Admin. L. Rev. 59, 60 (1995). One should note that guidance is an informal means of regulation whereby the FDA issues statements “advising” regulated entities on how to comply with FDA regulations and provisions of the Food, Drug, and Cosmetic Act

⁴5 U.S.C. §§ 501 *et seq.* (1946). The APA establishes the minimum procedures that agencies must follow when performing their adjudicatory or rulemaking functions. The APA divides agency actions into four categories: informal rulemaking, formal rulemaking, informal adjudication, and formal adjudication. §553 of the APA governs informal rulemaking. §§556-57 of the APA govern formal rulemaking and formal adjudication. §555 of the APA and the Due Process Clause of the Fourteenth Amendment govern informal adjudication.

⁵ADMINISTRATIVE CONFERENCE OF THE U.S., A GUIDE TO FEDERAL AGENCY RULEMAKING ix (2d ed. 1991) (found in the Chairman’s Foreword).

⁶*Id.*

policy through broad participation rather than to derive it from the facts of particular cases.

The Food and Drug Administration (“FDA”) followed this pattern. Prior to 1970, the FDA used primarily case-by-case court enforcement to ensure compliance with the policies and provisions of the Federal Food, Drug, and Cosmetic Act (“FDCA”).⁷ This regulatory approach worked only because the problems and issues facing the FDA prior to 1970 were less complex and onerous than those arising over the past-twenty five years. As such, the FDA changed its principle method of policymaking under the FDCA to rulemaking in the 1970’s.⁸

There is general consensus in the legal community on the desirability of agency policymaking through rulemaking rather than case-by-case adjudication.⁹ Professor Richard Pierce summarizes the benefits of rulemaking as follows:

(1) rules provide a valuable source of decisional standards and constraints on agency discretion; (2) rules enhance efficiency by simplifying and expediting agency enforcement efforts; (3) rules enhance fairness by providing affected members of the public easily accessible, clear notice of the demarcation between permissible and impermissible conduct and by insuring like treatment of similarly situated individuals and firms; (4) rulemaking enhances the quality of agency policy decisions because it focuses on the broad effects of alternative rules and invites participation by all potentially affected groups and individuals; (5) rulemaking enhances efficiency by allowing an agency to resolve recurring is-

⁷21 U.S.C. §§ 301 *et seq.* (1938).

⁸PETER B. HUTT AND RICHARD A. MERRILL, *FOOD AND DRUG LAW: CASES AND MATERIALS* 1236-37 (2d ed. 1991).

⁹R. PIERCE, S. SHAPIRO, AND P. VERKUIL, *ADMINISTRATIVE LAW AND PROCESS* § 6.4.1 (2d ed. 1992); Richard J. Pierce, Jr., *Two Problems in Administrative Law: Political Polarity on the District of Columbia Circuit and Judicial Deterrence of Agency Rulemaking*, 1988 Duke L.J. 300, 308 (1988). One should note that informal regulation such as issuing advisory letters, guidance, and guidelines is the least favored policymaking vehicle because it affords regulated parties no procedural protections and establishes no controls on the agency’s exercise of discretion.

sues of legislative fact once instead of relitigating such issues in numerous cases; (6) rulemaking enhances fairness by allowing all potentially affected members of the public to participate in the decisionmaking process that determines the rules that apply to their conduct; and (7) rulemaking enhances the political accountability and legitimacy of agency policymaking by providing the public, the President, and the Congress advance notice of an agency's intent to make major policy decisions and an opportunity to influence policies ultimately chosen by the agency.¹⁰

Thus, the modern approach to regulation taken by agencies, including the FDA, enjoyed strong support.¹¹ In fact, a leading commentator "proclaimed such notice and comment procedures to be 'one of the greatest inventions of modern government'".¹²

The increased use of rulemaking in the 1960's and 1970's was not without its problems however. By 1969, the volume of agency rules and the range of areas covered by those rules was enormous. In the 1970's, congressional delegations of authority to agencies continued in unprecedented numbers. By one count, Congress enacted 130 laws in that decade establishing new programs that required extensive agency rulemaking.¹³ Agencies soon had the power to regulate almost all classes of environmental problems, to regulate health and safety hazards in nearly every workplace, and to establish comprehensive consumer protection regulations.¹⁴ Those delegations of regulatory authority swept broadly across the economy, imposing significant costs on private industry.¹⁵

As a response, all three branches of government moved to "control"

¹⁰Pierce, *supra* note 3, at 59-60.

¹¹HUTT AND MERRILL, *supra* note 8, at 1236-37.

¹²ADMINISTRATIVE CONFERENCE OF THE U.S., *supra* note 5, at ix (quoting from an interview of K. Davis and W. Gellhorn by P. Verkuil in Chairman's Forward).

¹³CORNELIUS M. KERWIN, RULEMAKING: HOW GOVERNMENT AGENCIES WRITE LAW AND MAKE POLICY 14 (1994).

¹⁴*Id.*

¹⁵*Id.*

agencies' discretion to promulgate new rules and further burden the economy. Among other things, the courts adopted expansive definitions of the "concise general statement of basis and purpose" that must accompany every final agency rule. The courts also expanded the "arbitrary and capricious" standard of judicial review, thereby increasing an agency's duty to engage in reasoned decision making. Congress enacted a series of statutes requiring agencies to follow specific procedures in addition to those found in §553 of the APA when promulgating certain types of rules. Presidential involvement in the development of regulatory policies also increased in the 1980's and 1990's through Office of Management and Budget ("OMB") review of the rulemaking process.¹⁶

Commentators and agency insiders now believe that the cumulative weight of these constraints has "ossified" the rulemaking process.¹⁷ Many agencies today attempt to circumvent the rulemaking process by engaging in other forms of policymaking, such as case-by-case adjudication or, alternatively, the more informal types of regulation, such as issuing informal opinions, guideline or guidance documents, operating manuals, or even press releases.¹⁸

Parts II, III, and IV of this paper describe the major burdens placed on agency rulemaking by each branch of the government over the past thirty years, with specific focus on the burdens that presently affect FDA rulemaking.¹⁹ Part

¹⁶PIERCE, SHAPIRO, AND VERKUIL, *supra* note 9, at §6.4.6(d); ADMINISTRATIVE CONFERENCE OF THE U.S., *supra* note 5, at ix (found in the Chairman's Forward).

¹⁷CARNEGIE COMMISSION ON SCIENCE, TECHNOLOGY, AND GOVERNMENT, *supra* note 3, at 106-7. *See also, e.g.*, Pierce, *Seven Ways to Deossify Agency Rulemaking*, *supra* note 3.

¹⁸CARNEGIE COMMISSION ON SCIENCE, TECHNOLOGY, AND GOVERNMENT, *supra* note 3, at 107, 109.

¹⁹An anonymous FDA source provided lists of requirements with which the FDA must presently comply when it engages in rulemaking. From those, one set of requirements was compiled for the purposes of this paper.

V then analyzes the effect those burdens have had on FDA rulemaking. The analysis will demonstrate that the additional rulemaking requirements likely act to deter rulemaking at the agency. In conclusion, Part VI briefly discusses the type of policymaking in which FDA currently engages as an alternative to rulemaking and describes further research to be done regarding that method of FDA policymaking.

II. Burdens Imposed by the Judicial Branch

The APA establishes three basic procedural requirements for informal rulemaking: first, the publication of a general notice of proposed rulemaking; second, an opportunity for any interested party to submit a written comment about the proposal with the proposing agency; and third, a concise statement by the agency explaining its basis for adopting the final rule.²⁰ In addition, the APA provides for judicial review of final agency actions such as the adoption of a final rule. Judicial review determines “the lawfulness of a final rule in three respects: first, the agency’s compliance with procedural requirements; second, its legal authority to adopt the rule; and third, the factual support for and the rationality of the agency’s judgment”, otherwise known as arbitrary and capricious review.²¹

In the late 1950’s, rulemaking was an underutilized procedure and the courts leniently enforced its requirements. Professor Peter Strauss describes:

²⁰Peter L. Strauss, *From Expertise to Politics: The Transformation of American Rulemaking*, 31 Wake Forest L. Rev. 745, 752 (1996).

²¹*Id.*

The requirement of notice... could be satisfied by inclusion of “either the terms or the substance of the proposed rule or a description of the subjects and issues involved”²²... [a]nd the statutory requirements for findings, that “the agency shall incorporate in any rule it adopts a concise general statement of [its] basis and purpose”²³ was literally understood – a one or two page statement of the agency’s reasoning was [sufficient].²⁴

Judicial review became significantly more intense in the 1970’s and 1980’s in response to the substantial economic consequences of major regulation and the absence at that time of any political institutions to control the rulemaking process.²⁵ As one commentator noted, judicial review “transformed the simple, efficient notice and comment process into an extraordinary lengthy, complicated, and expensive process”.²⁶ The changes in the notice and comment process stem from broader judicial interpretations of the language in the APA. The new interpretations of “notice”, “comments”, “statement of basis and purpose”, and “arbitrary and capricious” now impose substantial burdens on agency rulemaking.²⁷

²²5 U.S.C. § 553(b)(3).

²³5 U.S.C. § 553(c).

²⁴Strauss, *supra* note 20, at 752-53.

²⁵*Id.* at 770. According to Professor Strauss, “scholars at that time talked openly of the judicial review process as a kind of substitute political process” and as a means of controlling the discretion exercised by administrators who were not subject directly to the constraints of electoral politics. *Id.* See also JERRY L. MASHAW AND RICHARD A. MERRILL, ADMINISTRATIVE LAW: THE AMERICAN PUBLIC LAW SYSTEM, CASES AND MATERIALS 317-18 (2d ed. 1985). This was especially important considering the tendency of Congress at that time to delegate broader and more general powers to agencies, most notably in the area of “social regulation” seeking to protect health, safety, and the environment.

²⁶Pierce, *supra* note 3, at 65. During that time period, only about half of all promulgated rules survived this new form of judicial review. *Id.*; Peter H. Schuck and E. Donald Elliot, *To the Chevron Station: An Empirical Study of Federal Administrative Law*, 1990 Duke L.J. 984, 1022 (1990) (during 1965, 1975, and 1984-85, reviewing courts upheld only 43.9% of agency rules). Today, courts seldom overturn an agency rulemaking for failure to comply with the APA’s notice and comment requirements, because although the rules are more stringent than they were in the late 1950’s, they also are relatively clear and predictable, making compliance easier for agencies. *Id.* at 1010. Also, *Chevron, Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984) (granting agencies the authority to interpret their own enabling statutes) makes attacking agency rules more difficult because courts have to defer to an agency’s interpretation of its statutes.

²⁷KENNETH C. DAVIS AND RICHARD J. PIERCE, ADMINISTRATIVE LAW TREATISE, VOLUME I § 7.1 (3d ed. 1994).

The change in the courts' perception as to what constitutes adequate notice under §553(b) of the APA impacted how agencies approach the informal rulemaking notice and comment process. Most challenges to the adequacy of agency notice arise because either (1) the proposed rule and the final rule are so different that parties affected by the final rule could not have known that the agency was considering one of the elements of the final rule; or (2) the agency supported its final rule with data that was unknown to affected parties until the agency announced its final rule. The same argument applies to both types of situations: parties cannot submit meaningful comments unless the notice of proposed rulemaking indicates the issues under consideration by the agency.²⁸

Courts developed the “logical outgrowth” doctrine to address the first concern. Under this test, a court may find notice of proposed rulemaking adequate, even if the final rule reflects substantial changes from proposed rule, so long as the final rule is a “logical outgrowth” of the proposed rule.²⁹ The idea is that if the final rule logically relates to the proposed rule then the public should have expected a rule in the form of the final rule, thus making the notice adequate. This doctrine attempts to address a tension inherent in notice and comment rulemaking. On the one hand, an agency cannot issue a final rule changing the state of regulation in an area where the proposed rule gives no warning that the agency was considering such changes.³⁰ On the other hand, an agency's final rule can differ substantially from the proposed rule so long as the agency's notice warns interested parties of the possibility that those changes

²⁸ *Id.* at §7.3.

²⁹ *See, e.g.,* American Medical Association v. U.S., 887 F.2d 760 (7th Cir. 1989).

³⁰ *See* Wagner Electric Corp. v. Volpe, 466 F.2d 1013 (3d Cir. 1972).

might occur.³¹ After all, the function of the notice and comment process is to give the agency an opportunity to make changes in its final rule in response to critical comments received by the public.

The “logical outgrowth” test is amorphous and leaves to the discretion of the reviewing court much of the decision as to what constitutes adequate notice. The consequence of this new notice requirement is that when an agency develops a final rule that does not logically relate to the proposed rule, it must reissue that rule in a notice of proposed rulemaking. The agency has to effectively repeat the notice and comment process.

In response to the second concern, courts came to interpret adequate notice as requiring an agency to include, as part of the notice of proposed rulemaking, data in the agency’s possession which forms the basis of its proposed rule.³² The courts reasoned that promulgating rules on the basis of inadequate data or data known only to the agency is “not consonant” with the purpose of notice and comment because there is no actual opportunity to comment on that data.³³

Further, data on which an agency bases its final rule is by definition relevant to the rulemaking. The lack of such data in the notice of proposed rulemaking fails to elicit significant comments related to the data that parties might have made had the data been included. These comments would have

³¹ See *South Terminal Corp. v. EPA*, 504 F.2d 646 (1st Cir. 1974).

³² See, e.g., *U.S. v. Nova Scotia Food Products Corp.*, 568 F.2d 240 (2d Cir. 1977) (invalidating FDA rule concerning minimum time and temperature for cooking whitefish because FDA supported its rule by referring to studies it did not mention in its notice of proposed rulemaking); *Portland Cement Ass’n. v. Ruckelshaus*, 486 F.2d 375 (D.C. Cir. 1973) (invalidating EPA rule because EPA used unpublished data to support its proposed and final rules which was not included in notice of proposed rulemaking).

³³ *Portland Cement*, 486 F.2d at 393.

been relevant to the rulemaking because they would have pertained to the data. Therefore, to the extent an agency bases the final rule on that data, the agency fails to consider “relevant factors” in its rulemaking decision. An agency acts arbitrarily and capriciously under the “hard look” doctrine described below when it adopts a rule and fails to consider “relevant factors” in its decision.

Perhaps the greatest change in the way agencies approach informal rulemaking stems from the development of “hard look” judicial review of final rules. §706(2)(A) of the APA mandates that a court set aside an agency action when the action is arbitrary and capricious. *Citizens to Preserve Overton Park, Inc. v. Volpe*³⁴ presents the first modern interpretation of the arbitrary and capricious standard of review. The Court concluded that to determine whether the agency’s action was arbitrary and capricious, it must consider whether the agency considered the “relevant factors” in its decision and whether the agency made a “clear error of judgment” in its decision.³⁵ The Court further stated that although a reviewing court’s inquiry into the facts must be “searching and careful”, the court cannot substitute its judgment for that of the agency.³⁶ The “searching and careful” standard described in *Overton Park* is often called “hard look” review and reviewing courts have applied that standard of review to agency rulemakings from the early 1970’s to the present.³⁷

³⁴401 U.S. 402 (1971).

³⁵*Id.* at 416.

³⁶*Id.* One should note that *Overton Park* has had a lasting impact on judicial review of rulemaking even though the agency action reviewed by the *Overton Park* Court was an informal adjudication and not an informal rulemaking.

³⁷It is important to note that “hard look” review has both procedural and substantive aspects to it. The requirement that the agency consider “relevant factors” in its decision is procedural because it prescribes how the agency is to proceed in making a decision. The “clear error of judgment” prong is substantive because it allows reviewing courts to actually decide whether the agency’s decision is reasonable in light of the facts in the rulemaking record.

A court evaluates the agency’s “concise general statement of basis and purpose” that accompanies each rule to determine whether the agency’s rulemaking is arbitrary and capricious.³⁸ Over the past twenty years, however, the courts have applied the “hard look” review standard to agency rulemaking in such a way that the adjectives “encyclopedic” and “detailed” have replaced the statutory adjectives of “concise” and “general”.³⁹ As summarized by Professor Richard Pierce:

To avoid reversal and remand of a rule, an agency must consider explicitly the consistency of its rule with each of the many inherently inconsistent goals Congress typically requires the agency to pursue. The agency also must consider explicitly the issues and arguments raised in comments submitted by potentially affected members of the public. In the case of a rulemaking to resolve a major policy issue, those comments typically encompass tens of thousands of pages, include numerous studies commissioned by interested parties, and raise hundreds of issues. In order to avoid reversal and remand, the agency’s discussion in the statement of basis and purpose must demonstrate that the agency has given full consideration to each issue and that it has balanced objectively each decisional factor.⁴⁰

No court today would uphold a substantial agency rule that incorporates only a truly “concise general statement of basis and purpose” of the type readily accepted by the courts in the 1950’s.⁴¹ To have any reasonable chance of

³⁸Pierce, *supra* note 9, at 309.

³⁹*Id.* See also Stephen Breyer, *Judicial Review of Questions of Law and Policy*, 28 Admin. L. Rev. 363, 393 (1986).

⁴⁰Pierce, *supra* note 9, at 309-10. See also *U.S. v. Nova Scotia Food Products Corp.*, 568 F.2d 240 (2d Cir. 1977) (holding that for judicial review to be meaningful, the statement of basis and purpose should enable a court to see what policy issues the notice and comment phase addressed and why the agency reacted to those issues the way it did).

⁴¹One should note that the Supreme Court’s ruling in *Vermont Yankee Nuclear Power Corp. v. Natural Resources Defense Council*, 435 U.S. 519 (1978) (holding that courts are not permitted to add procedures to informal rulemaking beyond those listed in §553 of the APA through common law reasoning) does not affect “hard look” review because the requirements of “hard look” review evolve from judicial interpretations of the arbitrary and capricious and statement of basis and purpose provisions of the APA and do not constitute common law additions to the procedures listed in §553 of the APA. The fact that the Supreme Court continued to apply “hard look” review to informal rulemaking after the *Vermont Yankee* decision shows that *Vermont Yankee* did not change “hard look” review. See, e.g., *Motor Vehicle Manufacturers Association v. State Farm Mutual Automobile Insurance Co.*, 463 U.S. 29 (1983).

surviving judicial review, an agency must provide the basis and purpose of its rule in a detailed statement meeting the above requirements. Such an endeavor often results in a final rule totaling several hundreds of pages in length.⁴²

The Supreme Court’s decision in *Abbott Laboratories, Inc. v. Gardner*⁴³ was significant not only because it adopted the doctrine of pre-enforcement review of agency rules, but also because it spurred the development of “hard look” review by the courts. Prior to that decision, the lawfulness of agency rules could be challenged only in an enforcement action brought by an agency. Courts typically reviewed rules based on the record developed during the agency’s enforcement proceeding. Most rules were upheld under this procedure. After *Abbott Laboratories*, most rules were subject to pre-enforcement review where the reviewing court only had the rulemaking record before it on which to judge the lawfulness of the rule. This new procedure forced courts to impose stringent demands on agencies to compile rulemaking records that would adequately support their rules – records demonstrating the agencies’ detailed consideration of data disputes and other significant comments, policy concerns, and reasonable alternatives to the proposed rule contained in the comments.⁴⁴ These demands now constitute the “hard look” review requirements described above.

A further effect of *Abbott Laboratories* is that it creates additional disincentive for agencies to promulgate rules beyond the disincentive created by “hard look” judicial review. Even after an agency completes the lengthy and tedious notice and comment process required by “hard look” review there is

⁴²DAVIS AND PIERCE, *supra* note 27, at 310.

⁴³387 U.S. 158 (1967).

⁴⁴Pierce, *supra* note 3, at 88-89.

no guarantee that the rule will go into effect because it might be challenged in a pre-enforcement review action. Usually, a party challenging a rule will move for a preliminary injunction to prevent the agency from implementing the rule. If the plaintiff wins the preliminary injunction motion, the agency often will abandon the rule entirely to avoid further litigation.⁴⁵ An agency is less likely to create policy through notice and comment rulemaking when there is no guarantee that its rules can be implemented at the end of the day, especially in light of the tremendous commitment of resources and time that promulgating a rule now requires. An agency is more likely to turn to quicker and less costly methods of policymaking such as case-by-case adjudication or even other less formal methods of policymaking.

“Hard look” review appears to have substantial impacts on FDA rulemaking. The most notable is that FDA rulemakers must carefully review and respond to all significant comments received from the notice and comment process in order to show that the final rule has been rationally thought out. The process can take several years especially in the case of a significant regulation where the FDA might receive thousands of comments. For example, one FDA employee currently working on a proposed rule to amend the FDA’s hearing aid sales regulations stated that the FDA issued an advanced notice of proposed rulemaking three years ago, receiving about 3,000 comments, and FDA employees are just finishing the review and analysis of those comments.⁴⁶

⁴⁵The FDA abandoned rules on numerous occasions under these circumstances. Telephone Interview with Tom Scarlet, Partner at Hyman, Phelps, and McNamara in Washington D.C., and Chief Counsel to the FDA from 1981-1989 (January 14, 1997).

⁴⁶Telephone Interview with Joseph Sheehan, Chief of the Regulatory Staff, FDA Center for Devices (January 16, 1997).

Others attest to the substantial differences between rulemaking in the early 1970's and present day rulemaking. For example, Mr. Richard Cooper, Chief Counsel to the FDA from 1977-1979, noted that in the 1950's, there were no substantial preambles⁴⁷ to FDA regulations but by the mid-1970's, drafting rules was "a lot of work" because of the need to carefully review the comments and then write a detailed analysis justifying why the FDA considered or did not consider each substantial comment in the FDA's final rule.⁴⁸ Another current FDA employee, who has been involved in rulemaking for the last twenty years, observed that FDA preambles have become "substantially longer" over the years. In the early 1970's, preambles were generally short, consisting of a paragraph or two highlighting the purpose of and justifications for the rule. Now, preambles have become "huge" primarily because the courts require greater responses to the comments.⁴⁹

From these accounts, one can conclude that the rigors of judicial review increase both the time and expense of FDA rulemaking.

III. Burdens Imposed by the Legislative Branch

The Congress also increased its interest in the rulemaking process during

⁴⁷A preamble is simply an introductory summary of a regulation and contains statement of the rule's basis and purpose.

⁴⁸Telephone Interview with Richard Cooper, Partner at Williams and Connolly in Washington D.C., and Chief Counsel to the FDA from 1977-1979 (January 14, 1997).

⁴⁹Telephone Interview with Edwin Dutra, Supervisory Consumer Safety Officer, FDA Office of the Commissioner (January 15, 1997). Mr. Dutra specifically cited the new tobacco regulations as an example of how detailed and lengthy final rules have become. *See* 61 Fed. Reg. 44396 (August 28, 1996) (final published regulations totaling over 200 pages).

the same time that courts began to more strictly scrutinize rulemaking. Rules for which compliance required tens or hundreds of millions of dollars of investment by industry at a time when high inflation and interest rates burdened the economy caught the attention of politicians and business leaders. As a result, Congress began enacting statutes that required agencies to consider the effects of their proposed rules and to include those effects in their calculi used to determine the substance of their final rules.⁵⁰

This section summarizes the statutes passed by Congress since the late 1960's that presently impact FDA rulemaking. These statutes place both substantive and procedural burdens on the agency rulemaking process. The majority of the statutes emphasize a specific area of Congressional concern and mandate that agencies consider the substantive effects of their proposed rules on those areas. As such, the statutes attempt to limit the discretion exercised by agencies when they promulgate rules by specifying the types of information administrators weigh in their rulemaking decisions. Further, each statute specifies procedures with which agencies must comply when rulemaking. These procedural mandates are in addition to those already required by the APA and they act to slow down the rulemaking process.

National Environmental Policy Act

Congress enacted the National Environmental Policy Act ("NEPA")⁵¹ in

⁵⁰Strauss, *supra* note 20, at 758.

⁵¹42 U.S.C. §§ 4321 *et seq.* (1969).

1969 which directs agencies to consider the potential environmental impact of their proposed rules where such rules may impact the quality of the environment. NEPA reflects a national concern for the environment and it puts forth procedural requisites to ensure agency consideration of environmental values when formulating policy. Agencies must include in their proposals for “major Federal actions significantly affecting the quality of the human environment”⁵² an environmental impact statement (“EIS”) addressing among other things, the environmental impact of the proposed action, any adverse environmental effects which cannot be avoided should the proposal be implemented, and alternatives to the proposed action.⁵³ The Act requires that, prior to making the EIS for a rulemaking, an agency consult with and obtain comments from any agencies with jurisdiction or expertise with respect to any environmental impacts at issue.⁵⁴ Agencies must establish procedures to ensure that all rulemaking decisions are made in accordance with the policies and objectives of NEPA,⁵⁵ and those procedures must include procedures for assessing the need for an EIS and for preparing and obtaining comments on the EIS.⁵⁶ Each agency must develop such procedures under the supervision of the Council on Environmental Quality (“Council”) which is also responsible for monitoring compliance with

⁵²The Council on Environmental Quality created as part of NEPA, is responsible for adopting regulations setting forth uniform standards for conducting environmental reviews that are binding on all agencies. Those regulations define “major” as reinforcing but not having a meaning independent of “significantly”. 40 C.F.R. § 1508.18. Those regulations define “significantly” according to the context and intensity of the environmental effects of the agency action. 40 C.F.R. §1508.27.

⁵³42 U.S.C. §4332(C).

⁵⁴*Id.*

⁵⁵40 C.F.R. § 1505.1

⁵⁶40 C.F.R. §1507.3.

the mandates of NEPA.⁵⁷

There are no categories of FDA rulemaking which automatically require the preparation of an EIS because there are no categories of rulemaking that necessarily have a significant effect on the environment.⁵⁸ The FDA prepares an Environmental Assessment (“EA”) for any proposed rule that it thinks may significantly affect the environment,⁵⁹ provided that the category of rule does not qualify for an exclusion from the EA requirement.⁶⁰ The FDA then evaluates the information in the EA to determine its accuracy and objectivity and whether the potential effects of the proposed regulation warrant the preparation of an EIS.⁶¹ When the FDA determines that the preparation of an EIS is necessary for a proposed rule, it publishes a Notice of Intent to prepare the EIS in the Federal Register. FDA files a draft EIS with the Environmental Protection Agency (“EPA”) and sends drafts to parties having an interest in the document. The FDA must also state in the notice of proposed rulemaking that the EIS is available upon request and the FDA must solicit comments, corrections, and additional information on the issues covered in the EIS from

⁵⁷ *Id.*

⁵⁸ 21 C.F.R. § 25.21(a).

⁵⁹ 21 C.F.R. §25.22(a)(19). One should note that there are certain categories of rulemaking for which the FDA automatically prepares an EA such as promulgating regulations relating to the control of communicable diseases and the interstate conveyance of sanitation. 21 C.F.R. §25.22(a).

⁶⁰ See 21 C.F.R. §§ 25.23 and 25.24 for exclusions from the EA requirement.

⁶¹ 21 C.F.R. §25.22(d). The EA is a public document which contains environmental and other pertinent information regarding a proposed rule. The EA must provide a basis for the FDA’s decision whether to prepare an EIS or a Finding of No Significant Impact (“FONSI”) and the analysis must be written so that the public can understand the FDA’s decision. 21 C.F.R. §§ 25.31(a) and (b). 21 C.F.R. §§ 25.31a - 25.31e specify the formats of the EA for various types of FDA actions. 40 C.F.R. §1502.10 provides detailed requirements for the preparation of the EIS and the FDA follows that format unless it determines that there is a compelling reason to do otherwise. 21 C.F.R. § 25.34.

all interested parties.⁶² The FDA prepares the final version of the EIS after reviewing comments on the draft EIS and the final EIS receives full consideration in the FDA's structuring of the final rule.⁶³

NEPA does not affect much FDA rulemaking because so many categories of rulemaking are exempt from the EA requirement under 21 C.F.R. §§ 25.23 and 25.24. Even when the FDA prepares an EA, rarely does the process result in a determination to prepare an EIS. In fact, the FDA has never prepared an EIS for a rulemaking.⁶⁴ However, preparing EA's does impact FDA rulemaking to a certain degree because it is a task that the FDA takes seriously and allocates time and resources towards.⁶⁵

Some commentators argue that the major effect of the EIS requirement has been to give environmental groups a means of delaying or enjoining agency actions they oppose by challenging an agency decision not to prepare an EIS or the adequacy of an EIS that the agency does prepare.⁶⁶ However, this tactic appears not to have had a major impact on FDA rulemaking.⁶⁷

Regulatory Flexibility Act

Congress passed the Regulatory Flexibility Act⁶⁸ ("RFA") in 1980 to force agencies to consider the potential impact of their proposed regulations on small business and other small entities such as small (not-for-profit) organiza-

⁶²21 C.F.R. § 25.42(b).

⁶³21 C.F.R. §§ 25.42(a) and (b)(4).

⁶⁴Dutra Interview, *supra* note 49.

⁶⁵*Id.*

⁶⁶MASHAW AND MERRILL, *supra* note 25, at 57-58.

⁶⁷*See* HUTT AND MERRILL, *supra* note 8, at 1312 ("Nepa has occasionally been invoked by parties opposing FDA action" and those attempts have proved largely unsuccessful).

⁶⁸5 U.S.C. §§ 601-12 (1980).

tions and small governmental jurisdictions.⁶⁹ The RFA reflects Congressional concern about the impact of regulation, particularly environmental and health regulation, on economic growth and the vitality of small business. It imposes three types of burdens on agencies: the preparation of a regulatory agenda,⁷⁰ the preparation of a regulatory flexibility analysis for any proposed rulemaking expected to have a significant economic impact on a substantial number of small entities,⁷¹ and the periodic review of existing regulations to reevaluate the need for any rules that significantly affect a substantial number of small entities.⁷²

The RFA requires each agency to prepare a regulatory flexibility agenda of rules that an agency expects to propose and are likely to have a significant economic impact on a substantial number of small entities.⁷³ Each agency must transmit the agenda to the Chief Counsel for Advocacy of the Small Business Administration for comment.⁷⁴ Further, each agency must publish its agenda semi-annually in the Federal Register, bring each agenda to the attention of small entities or their representatives, and invite comment on the agenda.⁷⁵ The purpose of these requirements appears to be to allow small business and other small entities the opportunity to influence agency rulemaking decisions by giving them access to agencies in advance of when agencies publish their notices

⁶⁹5 U.S.C. §§ 601(3)-(6).

⁷⁰5 U.S.C. § 602.

⁷¹5 U.S.C. §§ 603-04.

⁷²5 U.S.C. § 610.

⁷³The Act does not define what constitutes a “significant economic impact on a substantial number of small entities”. However, at least one commentator has analyzed the legislative history of the Act in an attempt to define the intended parameters of that phrase. See Paul R. Verkuil, *A Critical Guide to the Regulatory Flexibility Act*, 1982 Duke L.J. 213, 242-247 (1982).

⁷⁴5 U.S.C. § 602(b).

⁷⁵5 U.S.C. § 602(c).

of proposed rulemaking.

The RFA requires an agency to prepare an initial regulatory flexibility analysis describing the impact of its proposed rule on small business and small entities each time it engages in notice and comment rulemaking. The analysis must contain a description of any significant alternatives to the proposed rule that meet the objectives of the proposed regulation while minimizing the economic impact of the proposed rule on small entities.⁷⁶ The agency must publish the analysis in the Federal Register along with the proposed rule and the agency must give the analysis to the Chief Counsel for Advocacy.⁷⁷ Further, where a proposed rule will have a significant economic impact, the agency “shall assure that small entities have been given an opportunity to participate in the rulemaking” through the use of techniques such as advance notice of proposed rulemaking, direct notification to small entities of the proposed rule, and the holding of public hearings or conferences.⁷⁸

After the comment period on the proposed rulemaking closes, the agency must prepare a final regulatory flexibility analysis which must respond to issues raised by public comments regarding the initial analysis.⁷⁹ The analysis also must contain a description of each of the significant alternatives to the rule that meet the objectives of the final rule while minimizing the economic impact of the rule on small entities and a statement of the reasons why the agency

⁷⁶5 U.S.C. § 603(c).

⁷⁷5 U.S.C. § 603(a). One should note that an agency does not have to prepare the regulatory flexibility analysis if the head of the agency certifies that the rule will not, if promulgated, have a significant economic impact on a substantial number of small entities. 5 U.S.C. § 605(b).

⁷⁸5 U.S.C. § 609.

⁷⁹*Id.*; 5 U.S.C. § 604(a).

rejected each alternative.⁸⁰ The Act mandates consideration of regulatory alternatives that are less expensive for small business and small entities for the purpose of influencing the substance of the final agency rule. The agency is not required to send the final regulatory flexibility analysis to the Chief Counsel for Advocacy, but it must either publish the analysis with the final rule or make the analysis available to the public on request.⁸¹

Under the original Act, the Chief Counsel for Advocacy oversaw agency compliance with the regulatory flexibility requirements. The Chief Counsel's main enforcement mechanisms were publicity, the annual reporting to the President and Congress on agency compliance, and *amicus* appearances in court challenges to agency rules.⁸² However, Congress amended parts of the RFA as part of its Small Business Regulatory Enforcement Fairness Act⁸³ of 1996 ("SBREFA") because it found that federal agencies were not responsive enough to small business concerns and had too often ignored the requirements of the RFA.⁸⁴

To remedy this problem, SBREFA (also discussed *infra* pp. 28-31) allows small entities to seek judicial review of agency compliance with the RFA's requirements.⁸⁵ Such a challenge is a cause of action independent of a challenge to the final agency rule where the final regulatory flexibility analysis constitutes

⁸⁰5 U.S.C. §604(a).

⁸¹5 U.S.C. § 604(b).

⁸²ADMINISTRATIVE CONFERENCE OF THE U.S., *supra* note 5, at 108-09. One should also note that the final regulatory flexibility analysis constitutes part of the agency rulemaking record for the purposes of judicial review. 5 U.S.C. § 611(c).

⁸³Pub. L. No. 104-121, §201, 110 Stat. 847 (1996) [hereinafter *SBREFA*].

⁸⁴*See* SBREFA § 202.

⁸⁵*Id.* § 242. One should note that SBREFA makes other small changes in §§ 603 and 604 of the RFA. However, the major change that affects how agencies deal with the requirements of the RFA is the judicial review provisions added by SBREFA.

part of the rulemaking record subject to judicial review. If a court finds an agency to be out of compliance with the requirements of the RFA, the court must order the agency to take corrective actions to comply with those requirements and must remand the rule to the agency and defer the enforcement of the rule against small entities unless the court finds enforcement to be in the public interest.⁸⁶

Such a cause of action gives much more bite to the RFA and provides incentive for agencies to adhere to its requirements. In fact, FDA personnel believe that this amendment will impact the way the FDA and other agencies approach rulemaking. Because of the threat of judicial review, the FDA must make certain it does a thorough small entity impact analysis any time there is a chance that one of its rules will affect small business and other entities.⁸⁷

The Act also requires agencies to publish and implement a plan for reviewing all existing rules on a ten-year cycle to minimize any significant economic impacts that existing rules might have on small business and small entities.⁸⁸ The review must consider the continued need for the rule, the extent the rule duplicates or conflicts with other federal, state, or local regulations, and any changes in technological or economic changes that occurred since the last evaluation of the rule.⁸⁹

⁸⁶*Id.* § 242(a)(4).

⁸⁷Telephone Interview with Larry Braslow, Director of the Economics Staff, FDA Office of Policy and Evaluation (January 17, 1997). Note that this is not a problem for “significant” rules as defined by Executive Order 12,866 since the FDA includes the regulatory flexibility analysis as part of the economic impact analysis required under that Order. However, there are regulations that are not “significant” under the Executive Order that can still substantially affect small business and small entities. The FDA and other agencies must now take seriously the regulatory impact analyses required for these rules.

⁸⁸5 U.S.C. § 610(a).

⁸⁹5 U.S.C. § 610(b).

Paperwork Reduction Act

Congress enacted the Paperwork Reduction Act⁹⁰ in 1980. The Act reflected Congressional concerns regarding the impact of regulation on economic vitality similar to those that fueled passage of the RFA. The purpose of the Act was to minimize the burden of official record-keeping and reporting requirements necessary to comply with agency regulations. The Act required an agency to first obtain OMB approval before it could impose any new demands for information on the private sector in a proposed rule. For executive agencies like FDA, an OMB refusal to approve such a rule was final. The Act's purpose was to discourage new information demands and reduce the burden of regulatory paperwork on industry.⁹¹

Congress recently passed the Paperwork Reduction Act of 1995⁹² ("PRA") to amend the old statute. The thrust of the statute remains unchanged but the amendments substantially increase rulemaking burdens for agencies. First, the PRA requires each agency to create an internal office responsible for ensuring agency compliance with the policies of the Act.⁹³ The office must establish a process to evaluate fairly whether proposed collections of information should be approved in light of PRA policies and review each proposed rule requiring a collection of information before submission to OMB.⁹⁴

Second, an agency conducting notice and comment rulemaking must include its proposed collection of information as part of its notice of proposed

⁹⁰44 U.S.C. §3501 *et seq.* (1980).

⁹¹MASHAW AND MERRILL, *supra* note 25, at 60.

⁹²Pub. L. No. 104-13, 109 Stat. 163 (1995) [hereinafter *PRA*].

⁹³PRA § 3506(a).

⁹⁴*Id.* § 3506(c)(1).

rulemaking. The agency must solicit comment to evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency and to evaluate the agency's estimate of the burden of the proposed collection of information.⁹⁵

Further, for any proposed collection contained in a proposed rule, the agency must submit a copy of the proposed rule containing the collection proposal to OMB for review. The agency must certify that each collection of information submitted for review (1) is necessary for the proper performance of the functions of the agency; (2) reduces to the extent practicable the burden on parties who will provide information to the agency;⁹⁶ (3) informs those who must submit information to the agency of the reasons the information is being collected, the way the information will be used, and the estimated collection burdens on such parties;⁹⁷ and (4) has been developed by an office within the agency that has planned and allocated resources for the efficient management and use of the information to be collected.⁹⁸ OMB may then file public comments regarding the proposed collection within 60 days after the Federal Register publishes the notice for proposed rulemaking.⁹⁹ Within that time, if OMB determines that the collection of information is unnecessary for any rea-

⁹⁵ *Id.* §§ 3506(c)(2)(A) and (B).

⁹⁶ Especially with respect to small entities as defined in the RFA. The PRA encourages agencies to consider alternative means of information collection from small entities such as establishing different compliance or reporting requirements or timetables that take into account the limited resources of small entities. *Id.*

§ 3506(c)(3).

⁹⁷ *Id.* § 3506(c)(1)(B)(iii).

⁹⁸ *Id.* § 3506(c)(3).

⁹⁹ *Id.* § 3507(d)(1). One should note that before approving a proposed collection of information, OMB must determine whether the collection is necessary for the proper performance of the functions of the agency. Before making such a determination, OMB may give the agency and other interested parties an opportunity to be heard at a hearing or to submit statements in writing airing their views. *Id.* §3508.

son, the agency may not engage in the collection of information.¹⁰⁰

Fourth, the agency may adopt a final rule that includes a collection of information if OMB does not find the collection unnecessary, but the agency must explain in the final rule how the adopted collection of information responds to the comments filed by OMB and the public or the reasons why the agency rejected such comments.¹⁰¹ OMB, in its discretion, can disapprove any collection of information contained in a rule if (1) the agency fails to comply with the above requirements, (2) OMB finds within 60 days of publishing the final rule that the agency's response to OMB's comments about the proposed collection are unreasonable, or (3) OMB determines that the agency has substantially modified in the final rule the collection of information contained in the proposed rule and the agency has not met the above requirements for the modified collection of information.¹⁰²

The PRA also provides that OMB may not approve a collection of information for more than a period of three years.¹⁰³ An agency must apply for an extension of OMB approval of a particular collection of information by conducting the same internal review of the collection and solicitation of public comment regarding the collection as described above and then submitting the collection of information to OMB for review. Such a submission should include an explanation of how the agency has used the information that it has collected

¹⁰⁰ *Id.*

¹⁰¹ *Id.* § 3507(d)(2).

¹⁰² *Id.* § 3507(d)(4). One should also note that a decision by OMB to approve or not approve a collection of information contained in an agency rule is not subject to judicial review. *Id.* § 3507(d)(6).

¹⁰³ *Id.* § 3507(g).

under the rule in question.¹⁰⁴ If OMB disapproves a collection of information contained in an existing rule or recommends or instructs an agency to change the collection contained in an existing rule, the agency must undertake a rulemaking limited to consideration of changes to the collection of information contained in the rule and then submit the modified collection of information to OMB for approval or disapproval as described above.¹⁰⁵

The PRA greatly impacts FDA rulemaking to the extent FDA attempts to promulgate a rule imposing paperwork burdens on regulated parties. Several months of work analyzing the paperwork burdens must be done before publishing the proposed rule and submitting it to OMB for review. Then, the FDA can spend many additional months considering comments received on the proposed rule and drafting the final rule. FDA personnel believe that Congress passed this statute simply to create a roadblock to rulemaking because, in their eyes, its only purpose is to slow down the rulemaking process.¹⁰⁶

Unfunded Mandates Reform Act

Congress passed the Unfunded Mandates Reform Act¹⁰⁷ (“UMRA”) in 1995 to address the problem of enacting legislation and regulations that impose costs on state, local, and tribal governments and does not also provide financial resources to those entities to pay the cost of compliance with the legislation or regulations. Title II of the Act addresses agency rulemaking and requires an

¹⁰⁴ *Id.* § 3507(h).

¹⁰⁵ *Id.*

¹⁰⁶ Dutra Interview, *supra* note 49. FDA personnel also observe that the FDA largely ignored the 1980 version of the Paperwork Reduction Act. However, the increased OMB oversight role in the 1995 version of the Act has forced the FDA to adhere to the PRA’s requirements. Sheehan Interview, *supra* note 46.

¹⁰⁷ Pub. L. No. 104-4, 109 Stat. 48 (1995) [hereinafter *UMRA*].

agency that promulgates a “significant”¹⁰⁸ rule to prepare a cost-benefit analysis of the rule.¹⁰⁹ The analysis should include among other things the following: the costs imposed on State, local, and tribal governments and the private sector and the health, safety, and environmental benefits gained by the regulation, including the extent to which the imposed costs may be paid with Federal financial assistance and the extent to which there are available Federal resources to pay for the mandate;¹¹⁰ estimates by the agency of the future compliance costs of the mandate and any disproportionate budgetary effects that the mandate may have on particular regions of the nation, particular state, local, or tribal governments, or on particular segments of the economy;¹¹¹ and estimates by the agency of the effects of the mandate on the national economy such as productivity, economic growth, and the production of jobs.¹¹²

The UMRA requires each agency to develop a plan to involve small governments in the rulemaking process. The plan must include a means of providing notice to small governments of agency plans to establish regulatory requirements that may impose mandates on those governments, a means for those officials to provide meaningful input into the agency’s development of those requirements, and a means of informing, educating, and advising small governments on compliance with those requirements.¹¹³ The UMRA also re-

¹⁰⁸Defined as any regulation that may result in the expenditure by State, local, or tribal governments or by the private sector of \$100,000,000 or more in any year. UMRA § 202(a).

¹⁰⁹*Id.* One should note that this cost-benefit analysis is similar to the one required under Executive Order 12,866. As such, the analysis required under this Act can be prepared as part of the Executive Order 12,866 economic impact analysis. *Id.* § 202(c). In fact, the FDA typically prepares the UMRA analysis as a section of the impact analysis.

¹¹⁰*Id.* § 202(a)(2).

¹¹¹*Id.* § 202(a)(3).

¹¹²*Id.* § 202(a)(4).

¹¹³*Id.* § 203.

quires each agency to develop a process to permit elected officials of State, local, and tribal governments to provide meaningful input in the development of regulations that may potentially impose significant mandates on those governments.¹¹⁴ Further, the UMRA requires an agency to identify and consider a “reasonable number” of regulatory alternatives that achieve the objectives of the desired rule. From these alternatives, the agency should select the least burdensome rule for State, local, and tribal governments where the rule imposes an intergovernmental mandate or for the private sector where the rule imposes a private sector mandate.¹¹⁵

An agency must include in both its notice of proposed rulemaking and its final rule a written statement that includes the cost-benefit analysis described above and the extent of the agency’s prior consultation with elected representatives of the potentially affected State, local, and tribal governments. The agency must present a summary of the comments and concerns that those officials expressed to the agency and the agency’s evaluation of those comments and concerns.¹¹⁶

The UMRA limits judicial review to an agency’s failure to prepare the written statement described above for the proposed or final rule and an agency’s failure to develop a plan to involve small governments in the rulemaking process. However, a court can only compel the agency to prepare the written statement or plan; it cannot invalidate or enjoin a rule for an agency’s failure

¹¹⁴ *Id.* § 204.

¹¹⁵ *Id.*, § 205(a). This provision of the Act does not apply where the head of the affected agency publishes with the final rule an explanation of why the agency did not adopt the least burdensome method of achieving the objectives of the rule. *Id.* § 205(b).

¹¹⁶ *Id.* §§ 202(a)(5) and (b).

to adhere to these requirements. The principle means of ensuring that agencies comply with the mandates of the Act is OMB and Congressional oversight. OMB must submit an evaluation of agency compliance to Congress and include in the evaluation agencies and rulemakings that fail to adequately comply with the mandates of the UMRA.¹¹⁷

Small Business Regulatory Enforcement Fairness Act

Subtitle E¹¹⁸ of SBREFA provides for Congressional review of agency rulemakings. The import of this legislation is that it allows Congress to review and disapprove of agency rules before they become effective whereas, before, Congress could not pass legislation to overturn any agency rule it did not like until after the rule was already in effect. SBREFA applies to all agency rules as defined by §501 of the APA and therefore applies to interpretive rules and policy statements issued by agencies even though those rules are exempt from the notice and comment rulemaking process.

The Act requires an agency to supply Congress and the General Accounting Office (“GAO”) with a report containing a copy of the rule, including whether it is a “major” rule,¹¹⁹ and copies of all analyses made in the course of rulemaking such as those required under the Executive Order 12,866, the Unfunded Mandates Reform Act, and the Regulatory Flexibility Act.¹²⁰ A rule takes effect as otherwise provided under the law except in the case where the

¹¹⁷ *Id.* § 205(c).

¹¹⁸ SBREFA §251 (codified at 5 U.S.C. §§ 801-08 (1996)).

¹¹⁹ The Act defines a major rule as one that likely will have an annual effect on the economy of \$100,000,000 or more, a major increase in costs or prices for consumers, industry, or State and local government agencies, or a significant adverse effect on competition, employment, investment, or productivity. 5 U.S.C. § 804(2). Note that this is similar to the definition of a “significant” rule under Executive Order 12,866.

¹²⁰ 5 U.S.C. § 801(a)(1).

rule is a major rule.¹²¹ Such a rule takes effect on the latest of (1) the date occurring 60 days after the Congress receives the report from the agency described above or after the Federal Register publishes the rule, (2) if the Congress passes a joint resolution to disapprove the rule and the President vetoes the resolution, the earlier date on which either House of Congress votes and fails to override the veto or occurring 30 days after the Congress receives the veto; or (3) the date the rule would have otherwise taken effect but not for this Act.¹²²

The Act requires the GAO to provide to the relevant Congressional committees an assessment of the agency's compliance with the procedural steps required under the laws mentioned above within 15 days of receiving an agency's rulemaking report.¹²³ Within a period of time after receiving the GAO's assessment, any appropriate committee in either the House of Representatives or the Senate may generate a resolution of disapproval of the rule.¹²⁴ If both Houses of Congress adopt the resolution and the President signs the resolution or the Congress overrides the President's veto, the rule ceases to have legal effect. Should that happen, SBREFA further stipulates that the agency loses its authority to adopt a similar rule in the future unless authorized by new legislation.¹²⁵

SBREFA purportedly creates political responsibility in the legislative branch for agency rules having a significant impact on the economy. This fol-

¹²¹5 U.S.C. § 801(a)(4).

¹²²5 U.S.C. § 801(a)(3).

¹²³5 U.S.C. § 801(a)(2).

¹²⁴Note that § 802 of the Act provides the details of the Congressional disapproval process. This paper does not discuss the intricacies of that process because they are beyond the scope of the paper.

¹²⁵Strauss, *supra* note 20, at 769.

lows the pattern of increased executive branch scrutiny of agency rules described below. SBREFA, for the first time, also creates political responsibility for interpretive rules and policy statements. Those rules are not even subject to the notice and comment process mandated by §553 of the APA and therefore have no democratic foundation whatsoever.

However, at least one commentator does not paint such a “rosy view” of SBREFA and believes that it promises “to add further discouragement and expense to rulemaking at the agency level”.¹²⁶ First, the dynamic of the legislative process and the size of statutory enactments makes it easy for special interest to slip resolutions of disapproval into legislation, especially for non-major rules, interpretive rules, and policy statements since these are not high-profile agency actions.¹²⁷

Second, the Act only adds a layer of Congressional review to the rulemaking process without diminishing any of the review burdens now imposed on the rulemaking process. For example, SBREFA expressly prohibits a court from considering any action taken by Congress under SBREFA in its review of an agency rule.¹²⁸ The Act therefore leaves in place “hard look” review which the courts adopted because of the lack of political accountability in the rulemaking process.¹²⁹ With the increased review of agency rules by the political branches of the government, one would think that Congress might restrict judicial review of agency rules.¹³⁰ Professor Strauss predicts that “these impacts, together with

¹²⁶ *Id.*

¹²⁷ *Id.* at 769-70.

¹²⁸ 5 U.S.C. § 805.

¹²⁹ Strauss, *supra* note 20, at 770.

¹³⁰ Strauss, *supra* note 23 at 770.

the uncertainties about rulemaking effectiveness introduced by the simple fact of this process and the varying delays in effective date it may entail, will raise the costs of rulemaking further”, which, in turn, will discourage rulemaking by agencies.¹³¹

The effect of Congressional review on the FDA rulemaking process is unclear at this point in time. The Congressional review procedure is new and FDA has not been able to assess its effects.¹³²

IV. Burdens Imposed by the Executive Branch

The realization of the political importance of agency rulemaking in the early 1970’s also increased Presidential interest in controlling the outcomes of the rulemaking process, especially in light of the high inflation and interest rates that characterized the economic climate at that time.¹³³ As suggested by Professor Strauss, in light of the passage of NEPA which, for the first time, forced agencies to take into account potential environmental consequences of their rules in the rulemaking process, “it was not hard for the White House to see that it would also be useful for agencies to think forward about the possible economic consequences of and justifications for their major regulations”.¹³⁴

President Nixon’s “Quality of Life” review was the first executive oversight program for rulemaking. The program focused almost exclusively on EPA

¹³¹ *Id.* at 772.

¹³² Telephone Interview with William Shultz, Deputy Commissioner for Policy, FDA Office of Policy (January 17, 1997).

¹³³ Strauss, *supra* note 20, at 758.

¹³⁴ *Id.*

rulemaking. The program required EPA to send a summaries of new rules and possible alternatives to reviewing agencies like the Council on Wage and Price Stability (“CWPS”) which integrated comments and criticisms into the rules and transmitted them back to EPA. The process sometimes extended the rulemaking process for many months but had the perceived beneficial effect of bringing outside views of costs and alternatives to EPA.¹³⁵

President Ford’s Inflation Impact Statement program focused on the fiscal impact of agency rules. In Executive Order 11,821,¹³⁶ Ford authorized OMB to promulgate rules for determining whether a specific agency rule was “major” with respect to its potential effect on the economy. The Order required each agency to prepare an Inflation Impact Statement analyzing the costs of each major rule and submit it to OMB. Each statement had to contain an analysis of costs and inflationary effects of the rule compared to the benefits to be derived from the rule and a review of alternatives to the rule that the agency considered when formulating the rule. The weakness of this program was that it was decentralized in that it left the primary responsibility of impact assessment to the agencies and therefore would not influence policy choices made by the agencies as would a more external form of review.¹³⁷

President Carter, under Executive Order 12,044,¹³⁸ required agencies to prepare regulatory analyses of proposed agency rules and submit those analyses to OMB for review. For major regulations, the regulatory analysis had to

¹³⁵Harold H. Bruff, *The Reagan Era in Retrospect: Presidential Management of Agency Rulemaking*, 57 Geo. Wash. L. Rev. 533, 546-47 (1989).

¹³⁶39 Fed. Reg. 41501 (November 27, 1974).

¹³⁷Bruff, *supra* note 135, at 547.

¹³⁸43 Fed. Reg. 12661 (March 23, 1978).

contain a description of the problem the rule addressed, a description of the alternative ways that the agency considered to deal with the problem, an analysis of the economic consequences of each alternative, and an explanation as to why the agency chose the one alternative over the others. President Carter also created the Regulatory Analysis Review Group (“RARG”) which reviewed the half dozen most important rules proposed each year. RARG issued comments that the respective agencies were supposed to consider when drafting the final versions of those rules.¹³⁹

President Carter also created the Regulatory Council whose primary responsibility was to develop a Calendar of Federal Regulations which created an “analytical synopses” of major rules being developed by various agencies that were expected to substantially affect the economy. The Counsel used the Calendar for regulatory planning by identifying relationships among proposed rules from different agencies and coordinating plans to address interjurisdictional regulatory issues.¹⁴⁰

President Reagan initiated the most ambitious regulatory oversight program of all. Executive Order 12,291¹⁴¹ required executive agencies to adhere to cost-benefit principles when promulgating regulations. Every agency had to prepare a preliminary and a final Regulatory Impact Analysis for all “major” rules (those with a significant impact on the economy) which had to contain the projected costs and benefits of the proposed rule, the expected net benefits

¹³⁹Bruff, *supra* note 135, at 547-48.

¹⁴⁰*Id.* at 548-49.

¹⁴¹46 Fed. Reg. 13193 (February 17, 1981).

that would result from the regulation, and other potentially more cost-effective alternatives to the proposed rule with an explanation as to why the agency could not adopt the most cost-effective alternative. Further, the Order required every agency to adhere to certain general principles when developing a rule such as basing rulemakings on adequate information regarding the need for and the consequences of a proposed rule, developing rules to address regulatory priorities, and structuring rules to maximize net social benefit by comparing the costs and benefits of a rule to viable alternatives to that rule. Every agency had to submit each proposed major rule along with a preliminary Regulatory Impact Analysis to OMB for review sixty days before the agency published its notice of proposed rulemaking. The Order gave OMB the authority to require an agency to refrain from publishing its notice of proposed rulemaking if there were concerns about the preliminary impact analysis or the proposed rule.¹⁴²

President Reagan also enacted Executive Order 12,498¹⁴³ which established a “regulatory planning process” whereby each executive agency head had to submit to OMB a draft regulatory program summarizing the major rules the agency expected to develop within the upcoming year. OMB had to review the plans for consistency with administration policy and publish the plans. This Order, along with Executive Order 12,291, gave appointed agency heads and OMB more power over the early stages of the rulemaking process by reducing the ability of entrenched agency staff to initiate the development of a major

¹⁴²Bruff, *supra* note 135, at 549-51.

¹⁴³50 Fed. Reg. 1036 (January 4, 1985).

agency rule without the consent of higher-level agency officials.¹⁴⁴

Executive Order 12,866

President Clinton promulgated Executive Order 12,866¹⁴⁵ in 1993. It imposes substantive and procedural rulemaking burdens on executive agencies similar to those imposed by the Reagan executive orders. The Order first establishes its “principles of regulation” as including, among other things, the following: each agency must identify the problem that it intends to address with a promulgating a rule; each agency will examine whether existing regulations have contributed to the problem and whether those regulations should be modified to correct the problem; each agency must assess available alternatives to solving the problem apart from direct regulation; each agency must set regulatory priorities and in doing so should consider the degree and nature of risks within its jurisdiction; when an agency determines that direct regulation is the best method of achieving the regulatory objective, it must design its rule in the most cost-effective manner to achieve the regulatory objective; each agency must assess the costs and benefits of its intended regulation and must propose or adopt a regulation only upon a reasoned determination that the rules benefits justify its costs; and each agency must tailor its regulations to impose the least burden on society, including individuals, businesses of differing sizes, and other entities including small communities and governmental entities.¹⁴⁶

¹⁴⁴Bruff, *supra* note 135, at 551. Note that this is the type of phenomenon that could occur at an agency such as FDA where many of the staff are long-term employees and deeply believe in the agency’s mission. Proponents of this model of agency behavior perceive agency heads to be captives of their own staffs rather than politically powerful managers of their respective agencies. *Id.*

¹⁴⁵58 Fed. Reg. 51735 (September 30, 1993) [hereinafter *Executive Order 12,866*].

¹⁴⁶Executive Order 12,866 §1(b).

The Order then divides its regulatory management approach into three principal parts. First, the Order establishes a regulatory planning mechanism to (1) provide for the effective coordination of regulations, (2) maximize the resolution of potential conflicts at an early stage, (3) involve the public and State, local, and tribal governments in regulatory planning, and (4) ensure that new agency regulations promote the President’s regulatory priorities.¹⁴⁷

This part requires each agency to prepare a Regulatory Agenda describing all regulations under development or review as specified by the Office of Information and Regulatory Affairs (“OIRA”).¹⁴⁸ As part of the Agenda, each agency must prepare a Regulatory Plan listing the most important “significant”¹⁴⁹ proposed or final rules that the agency expects to issue in the upcoming fiscal year. Each agency head must approve the Plan which must contain the following: a statement of the agency’s regulatory objectives and how they relate to the President’s priorities; a summary of each proposed or final rule that the agency expects to issue and alternatives to those rules as well as their preliminary expected costs and benefits of each rule; and a statement of the need for each rule and how the rule will reduce risks to public health, safety, or the environment, as well as how the magnitude of the risk addressed by the rule relates to other risks within the jurisdiction of the agency.¹⁵⁰ Each agency must submit its Plan to OIRA for the purpose of coordinating regulatory plans of the

¹⁴⁷ *Id.* §4.

¹⁴⁸ *Id.* §4(b). Note that OIRA is part of OMB.

¹⁴⁹ Defined to include rules that may have one of the following effects: impose a cost on the economy of \$100,000,000 or more or adversely effect the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety; interfere with a regulation or action of another agency; or alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof. *Id.* §3(f).

¹⁵⁰ *Id.* §4(c).

various executive agencies. OIRA then annually publishes a Unified Regulatory Agenda, which includes each agency's Regulatory Plan, and makes the Agenda available to Congress, State, local, and tribal governments and the public so that they can contact the specific agencies concerning any issues they might have with any particular Plan.¹⁵¹

Second, the Order centralizes review of significant proposed and final regulations similar to Reagan's first executive order. The Order first requires each agency to provide to OIRA for review a list of its planned rulemakings indicating those which the agency believes are significant. The Order grants OIRA authority to determine that a planned rulemaking not designated as significant is in fact significant.¹⁵²

For each proposed rule designated by the agency or OIRA as significant, an agency must provide to OIRA the text of the draft regulation with a summary of the need for the regulation and an explanation as to how the proposed regulation promotes the President's priorities.¹⁵³ Further, the agency must provide (1) an assessment, including the underlying analysis, of the benefits expected from the proposed rule and a quantification of those benefits where feasible,¹⁵⁴ (2) an assessment, including the underlying analysis, of the

¹⁵¹*Id.* Note that making the Uniform Regulatory Agenda available for comment encourages interested parties to negotiate rulemaking initiatives with the executive agencies before the notice and comment procedure even begins. The purpose of this program appears to be to develop a more consensus-oriented approach to regulation. The Order further enforces the consensus-oriented approach to regulation by requiring agencies to explore consensual mechanisms for developing regulations, including negotiated rulemaking. *See Id.* §6(a)(1).

¹⁵²*Id.* §6(a)(3)(A).

¹⁵³*Id.* §6(a)(3)(B).

¹⁵⁴The Executive Order lists the efficient functioning of the economy and private markets, the enhancement of health and safety, the protection of the environment, and the reduction or elimination of discrimination or bias as benefits that might result from a rule. *Id.* §6(a)(3)(C)(i).

costs expected from the proposed rule and a quantification of those costs where feasible,¹⁵⁵ and (3) an assessment, including the underlying analysis, of the costs and benefits of potentially effective and reasonably feasible alternatives to the proposed rule and an explanation why the proposed rule is preferable to those alternatives.¹⁵⁶ OIRA then has 90 days to review each submission to determine whether the proposed rule is consistent with the President's priorities and the principles of regulation described above. OIRA has the authority to return the proposed rule to the issuing agency for further consideration of some or all of its provisions but must provide a written explanation for returning the rule.¹⁵⁷

An agency must also submit to OIRA for review each final rule designated by the agency or OIRA as significant. The agency must include the same types of assessments with its final rule submission as required for the proposed rule submission described above. Again, OIRA has the authority upon review to return the final rule to the issuing agency for further consideration of some or all of its provisions.¹⁵⁸

¹⁵⁵The Order lists the direct costs to both the government in administering the regulation and business in complying with the regulation, and any adverse effects on the efficient functioning of the economy, private markets, health, safety, and the environment as costs that might result from a rule. *Id.* §6(a)(3)(C)(ii).

¹⁵⁶*Id.* §6(a)(3)(C)(iii).

¹⁵⁷*Id.* §6(b)(3).

¹⁵⁸One should note that no agency action taken under this executive order or others described below is subject to judicial review or has any bearing on the judicial review of a rule. *Id.* §10. OMB oversight is the sole means of ensuring compliance with the provisions of the executive orders. At first blush it would seem that an agency that did not want to perform a cost-benefit analysis for a rule or wanted to ignore OMB concerns about the provisions of a rule could simply ignore the executive order. However, as a practical matter, the dynamic between OMB and the executive agencies precludes agencies from having that type of attitude about OMB's rulemaking oversight. There is a strong sense of professionalism in public administration where agency personnel appreciate the role of OMB as an executive agency representing the views of the President. Agency personnel have an obligation to pay attention when OMB has a concern about a rule and they usually act accordingly. If there is a real dispute among the low level bureaucrats at the agency and OMB, the issue can escalate to the political appointees at both the agency and OMB. At this level, personnel at both the agency and OMB know that they are Presidential appointees and that they are there to serve the President. As

Third, the Order requires agencies to establish and submit a program to OIRA for the periodic review of existing significant regulations to determine whether the rules have become unjustified or unnecessary, to confirm that the rules are compatible with each other and not duplicative in the aggregate, and to ensure that the rules are consistent with the President's priorities and the principles of regulation described above.¹⁵⁹ When an agency selects a significant regulation for review, the agency must include that rule in its annual Regulatory Plan for that year. The Order also requires an agency to identify any legislative mandates that require the agency to promulgate or continue to impose rules that the agency believes are unnecessary or outdated. The Order specifically encourages State, local, and tribal governments to assist in the identification of regulations that impose significant or unique burdens on them and that appear no longer justified or otherwise inconsistent with the public interest.¹⁶⁰

Based on anecdotal accounts from FDA employees, Executive Order 12,866 seems to significantly impact FDA rulemaking. Those accounts, however, reveal that OMB cost-benefit review of rules has both positive and negative effects on the rulemaking process. For example, one employee who oversees most of the economic impact analyses done for FDA rulemaking believes that analyzing the effects of the rules is an educational exercise for the agency. Without a cost analysis, the agency has no means or incentive to think through the steps

such, the appointees resolve the issue by determining what the outcome should be based on the philosophy of the current administration's regulatory program. Telephone Interview with Professor Christopher Edley, Jr., Professor of Law at the Harvard Law School, and Associate Director for Economics and Government at OMB from 1993-1995 (January 19, 1997). One should further note that OMB rulemaking oversight cuts down on rogue agency staff behavior. *See supra*, note 144.

¹⁵⁹ *Id.* §5.

¹⁶⁰ *Id.* §5(a).

that compliance will demand and the effects of such compliance on regulated parties. The FDA has changed many rules after performing the economic analyses because the agency realized that some provisions of its draft regulations were unmanageable and overly burdensome.¹⁶¹ Further, as one FDA employee suggested, the economic impact analysis requirement makes the agency think more about the need of a particular rule. The requirement forces the FDA to ask itself whether the rule is important enough to warrant the time and resource commitment needed to do an impact analysis.¹⁶²

On the other hand, economic impact analyses appear to be time-consuming and expensive. For example, for the recently enacted food labeling regulations,¹⁶³ the economic impact analysis took a group of FDA economists along with economists from an outside consulting firm a year to complete at a cost of approximately \$500,000.¹⁶⁴ Similarly, an economic impact analysis recently completed for a fish products processing rulemaking totaled over 100 pages and took over a year to compile.¹⁶⁵ Further, some FDA personnel (as well as many commentators) question whether OMB uses the cost-benefit review as a tool to produce better-focused and cost-effective regulations or as a means of stagnating the rulemaking process by demanding that the FDA and other agencies quantify the unquantifiable expected benefits of a regulation before granting approval of the regulation.¹⁶⁶

¹⁶¹Braslow Interview, *supra* note 87.

¹⁶²Telephone Interview with Philip Spiller, Director of the Office of Seafood, FDA Center for Food Safety and Applied Nutrition (January 16, 1997).

¹⁶³58 Fed. Reg. 2066-2964 (June 6, 1993).

¹⁶⁴Braslow Interview, *supra* note 87.

¹⁶⁵Spiller Interview, *supra* note 162.

¹⁶⁶*Id.*

Other Executive Orders

There are additional executive orders that impose specific procedural burdens on the rulemaking process for executive agencies. President Reagan enacted Executive Order 12,606¹⁶⁷ in 1987 which requires agencies to assess the impact that their rules might have on family formation, maintenance, and well-being. The Order establishes criteria that agencies should consider in their assessments¹⁶⁸ and requires each agency head to certify that each rule has been analyzed in accordance with those criteria. OMB oversees compliance with the Order.¹⁶⁹

President Reagan promulgated Executive Order 12,612¹⁷⁰ in 1987 which requires executive agencies to consider federalism principles when structuring their rules. The Order mandates an agency to adhere to the “fundamental federalism principles”¹⁷¹ when making a rule and for the agency to create a Federalism Assessment whenever a rule is likely to have sufficient federalism implications. The Assessment must certify that the agency evaluated its rule in light of the principles and purposes of the Order, identify any provision of the

¹⁶⁷52 Fed. Reg. 34188 (September 9, 1987) [hereinafter *Executive Order 12,606*].

¹⁶⁸Criteria include the following: does the rule strengthen or erode the stability of the family; does the rule help the family perform its function, or does it substitute governmental activity for that function; does the rule increase or decrease family earnings; do the proposed benefits of the action justify its impact on the family budget; and what message does the rule send to young people concerning behavior and personal responsibility. Executive Order 12,606 §1.

¹⁶⁹*Id.* §2.

¹⁷⁰52 Fed. Reg. 41685 (October 26, 1987) [hereinafter *Executive Order 12,612*].

¹⁷¹The principles include, among other things, the following: federalism is rooted in the knowledge that political liberties are best assured by limiting the size and scope of the federal government; all sovereign powers belong to the States except those delegated to the federal government in the Constitution; the nature of our constitutional system encourages a healthy diversity in the public policies adopted by the people of the several States according to their own conditions, needs, and desires; and that acts of the federal government cannot exceed the enumerated powers of the federal government under the Constitution. Executive Order 12,612 §3.

rule that is inconsistent with the principles and purposes of the Order, identify the extent to which the rule imposes additional costs on the States, and identify the extent to which the rule might affect the discharge of traditional state government functions.¹⁷² Every agency head must consider these Assessments in all rulemaking decisions.¹⁷³ The Order also provides that OMB has the authority to “take action” to ensure that agency rulemakings are consistent with the principles and requirements of the Order.¹⁷⁴

President Reagan also enacted Executive Order 12,630¹⁷⁵ in 1988 which requires all executive agencies when developing regulations to consider Fifth Amendment takings law so that agencies can avoid imposing regulatory burdens that might constitute takings. The Order establishes “takings principles”¹⁷⁶ and each agency that implements a regulation having takings implications must adhere to those principles. Each agency must further make certain that any restriction of private property is not disproportionate to the extent to which the use of that property contributes to the overall regulatory problem. If the restriction is to protect public health and safety, the agency should include in any submissions to OMB (such as the economic impact analysis or Federalism Assessment) a description of the public health or safety risk created by the pri-

¹⁷²*Id.* §6(c).

¹⁷³*Id.* §6(b).

¹⁷⁴*Id.* §7(a).

¹⁷⁵53 Fed. Reg. 8859 (March 15, 1988) [hereinafter *Executive Order 12,630*].

¹⁷⁶The principles include, among other things, the following: agency officials should be sensitive to and account for the Just Compensation Clause of the Fifth Amendment when formulating regulations; actions undertaken by the federal government that result in physical invasion or occupancy of private property or regulations that substantially affect the value or use of private property may constitute a taking of property; and government actions taken specifically for purposes of protecting public health and safety are usually given broader latitude by the courts before such actions are considered to be a taking. Executive Order 12,630 §3.

vate property use, an explanation of how the rule advances the protection of public health or safety, a showing that the regulation is not disproportionate to the extent the use of the property contributes to the overall regulatory risk, and an estimate of the cost to the government in the event that a court finds the regulation to be a taking.¹⁷⁷ Further, each agency must include in all required rulemaking submissions to OMB the takings implications of a proposed rule and the agency should also identify and discuss those implications in its notice of proposed rulemaking.¹⁷⁸ The Order authorizes OMB to “take action” to ensure that agency rulemakings are consistent with the principles and requirements of the Order.¹⁷⁹

President Clinton enacted Executive Order 12,875¹⁸⁰ in 1993 for the purpose of reducing the imposition of unfunded mandates on State, local, and tribal governments. Agencies must adhere to the provisions of this order as well as those contained in the Unfunded Mandates Reform Act of 1995 discussed above. The Order prohibits an executive agency from promulgating any regulation that is not required by statute which creates a mandate upon a State, local, or tribal government unless (1) the Federal government provides the funds to pay for the mandate; or (2) the agency, prior to developing its regulation, provides to OMB a description of the agency’s consultation with State, local, and tribal governments about the regulation, the nature of the concerns of those entities and any written comments from those entities received by the agency,¹⁸¹

¹⁷⁷ *Id.* §2.

¹⁷⁸ *Id.* §5(b).

¹⁷⁹ *Id.* §5(e).

¹⁸⁰ 58 Fed. Reg. 58093 (October 26, 1993) [hereinafter *Executive Order 12,875*].

¹⁸¹ Executive Order 12,875 §1(a).

and a statement of the need for the agency to issue the proposed rule in question. The Order also requires each agency to develop an effective communication process that enables representatives from State, local, and tribal governments to provide input into the development of rules that create significant unfunded mandates.¹⁸²

Lastly, President Clinton promulgated Executive Order 12,988¹⁸³ in 1996 for the purpose of improving access to courts and administrative tribunals for all persons wishing to resolve disputes grounded in administrative regulations. The Order establishes principles¹⁸⁴ that agencies must follow when promulgating rules in order to reduce the litigation burden on the courts. Further, the Order instructs an agency to review each proposed rule and final rule to ensure, among other things, that the rule specifies its preemptive effect and its effect on existing laws and regulations, provides a clear legal standard for affected conduct, specifies its retroactive effect, and specifies whether administrative proceedings are required before a party can file a suit in court under the rule.¹⁸⁵

V. The Effects on FDA Rulemaking

The principle concern is determining what effect the cumulative burden the

¹⁸²*Id.* §1(b).

¹⁸³61 Fed. Reg. 4729 (February 5, 1996) [hereinafter *Executive Order 12,988*].

¹⁸⁴The principles include, among other things, the following: the agency should review all rules for drafting errors; the agency should write rules to minimize litigation; and the rule should provide a clear legal standard for affected conduct rather than a general standard. Executive Order 12,988 §§ 3(a) and (b)(2).

¹⁸⁵*Id.* §3(c).

various rulemaking requirements has on the FDA rulemaking process. The hypothesis underlying this paper is that the cumulative burden deters FDA rulemaking and increases the number of situations where rulemaking is not a viable method of regulation. Unfortunately, there is no practical way to quantify the effects that the requirements have on FDA rulemaking either individually or cumulatively. Further, no one appears to have compiled empirical data on this question.¹⁸⁶ This analysis therefore uses anecdotal accounts to support the above hypothesis.

The most compelling accounts are those of Tom Scarlet¹⁸⁷ who was Chief Counsel of the FDA from 1981-1989. In a telephone interview, he stated that he could verify the truth of this paper's hypothesis that the procedural requirements have substantially burdened FDA rulemaking. The burdens began increasing in the beginning of the 1970's with the transformation of judicial review of agency rulemaking and continued into the 1980's with OMB cost-benefit review of rules, all of which made rulemaking difficult.

Mr. Scarlet cited an "invisible" burden as having one of the greatest impacts on the rulemaking process; namely, review of FDA proposed and final rules by the Department of Health and Human Services ("HHS").¹⁸⁸ As Mr. Scarlet explained, HHS became involved in FDA rulemaking when OMB began

¹⁸⁶Telephone Interview with David Plocher, Minority Counsel, Senate Government Affairs Committee (January 21, 1997); Telephone Interview with Gary Bass, Executive Director, OMB Watch (January 17, 1997); Telephone Interview with David Vladeck, Litigation Attorney, Public Citizen (January 15, 1997).

¹⁸⁷See *supra* note 47.

¹⁸⁸Note that HHS promulgated a regulation stating that the Secretary of HHS "reserves the authority to approve [FDA] regulations" which create rules governing a class of products or address important public policy issues. 21 C.F.R. § 5.11; HUTT AND MERRILL, *supra* note 8, at 1245.

its oversight of executive agency rulemaking, and is concerned especially with the cost-benefit review of proposed and final agency rules. As a political matter, HHS did not want anything going to OMB from its sub-agency without first reviewing it. As a result, the FDA had to send all proposed and final agency rules to the Office of the Assistant Secretary of Health for review before the rules could be sent to OMB.¹⁸⁹

According to Mr. Scarlet, the layer of HHS review had a dramatic effect on the rulemaking time line. HHS frequently sent rules back to FDA for changes before it allowed the FDA to send them to OMB. HHS review often took months or even a year to complete. Delays sometimes extended the review process for more than a year. Moreover, each rule had to go through HHS review twice, once as a proposed rule and once as a final rule; thus, often extending FDA rulemaking by two to three years. The political price of HHS review was also high. FDA officials had to placate HHS officials to get a proposed or final rule through HHS quickly. This meant that FDA had to compromise on the substance of its rules without any real debate or negotiation in order to avoid conflict with HHS officials.

The delay and the political toll both provided further disincentive to engage in rulemaking. In the early 1970's, judicial review was not as demanding and there was no HHS or OMB review. The picture was far different in the 1980's. Publishing the notice of proposed rulemaking could take a year or two because both of HHS and OMB review of the proposed rule. Writing the final

¹⁸⁹This was the structure of the HHS review process in the 1980's when Mr. Scarlet worked at the FDA. This analysis assumes that the same review structure still exists.

rule could take a year or two because FDA had to review and respond to each significant comment to satisfy judicial requirements. Publishing the final rule could take another year or two because of a second review by both HHS and OMB. Finally, if there was a pre-enforcement challenge to a rule, the courts tied up the rule for another year or two before it could become effective. In total, it took an additional five years or more for FDA to promulgate a rule because of the burdens added to the rulemaking process in the 1970's and 1980's.

Mr. Scarlet gave two examples where HHS review caused FDA rule-making to stagnate. First, in the early 1980's, FDA wanted to establish a new drug approval system. FDA sent its proposed regulation to HHS but could not convince HHS to send the rule to OMB because HHS economists and management analysts kept reviewing and changing parts of the rule. The proposal never left HHS. Instead someone leaked it to Capitol Hill and the proposed rule became part of the 1984 Waxman-Hatch Law. Congress took about one year to pass that legislation. Mr. Scarlet speculated that had Congress not gotten involved, FDA would not have been able to implement its regulation until the 1990's. Second, in the late 1980's FDA began promulgating a new food labeling regulation. Again, HHS review tied up FDA's proposed rule. Finally, Congress got involved and passed the 1990 Nutrition Labeling and Education Act, again incorporating many of the provisions contained in FDA's proposed regulation. Mr. Scarlet again speculated that had Congress not involved itself in this matter, the new food labeling regulations would still not exist.¹⁹⁰

¹⁹⁰Mr. Scarlet does not think that HHS and OMB oversight tie down every FDA regulation. He stated that rules get through the reviews process quickly if external political pressures

Joseph Sheehan, Chief of the Regulatory Staff in the FDA's Center for Devices, also presented a compelling account of the effects that these procedural burdens have had on the FDA rulemaking process.¹⁹¹ The first project that Mr. Sheehan worked on upon joining FDA in 1976 was a rulemaking for regulating the sale of hearing aids. That rule essentially requires that a hearing aid dispenser not sell a hearing aid unless the prospective user has a written statement from a physician confirming that person's hearing loss and need for a hearing aid. The rule contains a waiver provision whereby the user can waive the requirement of the physician statement if the dispenser believes that a waiver is in the user's best health interest.¹⁹² According to Mr. Sheehan, less than a year elapsed between the time the FDA published the notice of proposed rulemaking and the final rule.

Currently, the FDA is trying to amend the hearing aid sales regulation to eliminate the personal waiver provision because FDA investigations uncovered that 80%-90% of users were waiving the physician statement requirement due to misleading encouragement by hearing aid dispensers. The FDA published an advance notice of proposed rulemaking three years ago and has yet to publish its notice of proposed rulemaking. FDA received over 3,000 comments from the advanced notice which FDA must review and respond to in its notice of proposed rulemaking to satisfy judicial notice requirements. Further, FDA has to complete its economic impact analysis for OMB as well as assessments

drive the rulemaking. Most review problems occur when FDA initiates the rulemaking under its own discretion. Scarlet Interview, *supra* note 45.

¹⁹¹Sheehan Interview, *supra* note 46.

¹⁹²*See* 21 C.F.R. § 801.421.

required by the Paperwork Reduction Act and the Unfunded Mandates Act before it can publish the notice of proposed rulemaking. The FDA hopes to publish the notice of proposed rulemaking this year. Mr. Sheehan expects that there will be a delay of at least a few more years before the FDA can publish its final rule. This account demonstrates that what once took a year or two to complete in the 1970's now requires an investment of five or six years because of the increased burdens on the rulemaking process.

The above anecdotes and other accounts contained in the Parts II, III, and IV of this paper illustrate the time-consuming and expensive nature of the burdens on FDA rulemaking, substantially lowering its value as a feasible method of policymaking. First, time cycles become a problem. Many of the FDA-regulated industries are technologically sophisticated; new regulatory issues arise in those industries with every new technological advancement. Arguably, rulemaking has become an impractical means of regulating those areas for two reasons. One is that an urgent regulatory issue that needs to be solved within a year cannot be solved by a rulemaking that takes five or more years to complete. The second is that even if a regulatory issue does not need immediate attention, by the time the FDA completes a rulemaking to address that issue, the rule may be moot. Such would be the case if a technological change negates the original issue and creates a second issue that the rule is not designed to address. The probability that either of these scenarios will occur increases as the rulemaking process takes longer to complete.

Rulemaking also has become increasingly expensive. The burdens de-

scribed throughout this paper require the FDA to allocate far more resources towards rulemaking in the 1990's as compared to what was required in the early 1970's. For example, the FDA had to hire an economic staff to deal with the analyses required under the Regulatory Flexibility Act and Executive Order 12,866,¹⁹³ and environmental experts to deal with the environmental assessments required under NEPA.¹⁹⁴ Moreover, the FDA must devote personnel and resources to the task of reviewing and addressing comments received during the notice and comment process. This task often takes years,¹⁹⁵ and those assigned to it cannot work on other projects. The FDA must therefore hire additional personnel to handle the residual workload. The current expense of rulemaking makes it an increasingly untenable form of policymaking for the FDA in today's political climate where government agencies face ever-increasing budget constraints. In short, the developing trend is that the FDA cannot afford to continue to use rulemaking as its principle means of policymaking.

The above anecdotes and arguments support the hypothesis that the burdens of rulemaking deter the FDA from using rulemaking as a regulatory instrument. Assuming that the hypothesis is true, one must determine the method of regulation the FDA uses in place of rulemaking. Further investigation may reveal that the FDA has turned to the use of guidance¹⁹⁶ to fill the policymaking void left in the absence of rulemaking.

¹⁹³Braslow Interview, *supra* note 87.

¹⁹⁴Dutra Interview, *supra* note 49.

¹⁹⁵*See, e.g.*, Sheehan Interview, *supra* note 46.

¹⁹⁶*Supra* note 3.

VI. Conclusion

The burdens imposed on agency rulemaking by “hard look” judicial review, NEPA, the Regulatory Flexibility Act, the Paperwork Reduction Act, the Unfunded Mandates Act, and the various executive orders, especially Executive Order 12,866, have led to the “ossification” of rulemaking at the FDA. The threat of Congressional review imposed by SBREFA only serves to exacerbate this phenomenon. As a result, the FDA probably no longer uses rulemaking as its principle method of policymaking. This paper suggests that the FDA now uses informal guidance as a substitute for rulemaking.

Such a trend is problematic for several reasons. First, there are concerns about whether the FDA uses a guidance as an informational tool or as a de facto rule. A frequent complaint by industry is that the FDA enforces guidance statements as if they were legally binding rules.¹⁹⁷ For example, the FDA sends a letter notifying a company about steps it should take to comply with a particular Good Manufacturing Practice (“GMP”) regulation. If the company does not change its practices as suggested by the guidance letter, the FDA inspector might shut down the company’s manufacturing operations for being out of compliance with the GMP. Arguably, this practice is illegal because the FDA treats the guidance as a rule but did not promulgate it using notice and comment procedures as required by the APA.

Second, the FDA exercises great discretion when it regulates using

¹⁹⁷Telephone Interview with Nancy Buc, Partner at Buc and Beardsley in Washington D.C., and Chief Counsel to the FDA from 1980-1981 (January 23, 1997); Telephone Interview with Bradley Thompson, Partner at Baker and Daniels in Indianapolis, IN (October 19, 1996).

guidance. One of the functions of rulemaking is to control an agency's discretion by developing rules that legally bind agencies to act in a specific way and follow stated policies. Without rulemaking, there is no way to control potential abuses of discretion by the FDA.

Third, rules inform regulated parties as to how they should behave under the law, whereas a regime of informal regulation has no clearly defined modes of behavior. The use of guidance creates uncertainty for regulated parties who must guess as to how to behave within the law. This uncertainty is also bad for the public interest because, without rules, regulated entities have difficulty self-regulating and may therefore engage in socially harmful behavior.

This paper is the first part of a broader investigation into the FDA's current use of guidance as a regulatory tool. This paper demonstrates that rulemaking has become increasingly burdensome for the FDA over the past twenty-five years and hypothesizes that this has caused the FDA to increase its use of guidance as an alternative to rulemaking. Future work will explore the FDA's current use of guidance, and will analyze the problems caused by its use, and their potential solutions.